

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

<b>IN RE: DAVOL, INC./C.R. BARD, INC.,</b>	)	
<b>POLYPROPYLENE HERNIA MESH</b>	)	<b>Case No. 2:18-md-2846</b>
<b>PRODUCTS LIABILITY LITIGATION</b>	)	
	)	<b>CHIEF JUDGE EDMUND A. SARGUS, JR.</b>
	)	<b>Magistrate Judge Kimberly A. Jolson</b>
<b>This document relates to:</b>	)	
<b>ALL CASES.</b>	)	

**DEFENDANTS C. R. BARD, INC. AND DAVOL INC.'S BRIEF CONCERNING  
PROPOSED CMO (PROTECTIVE ORDER)**

**I. INTRODUCTION**

Protective orders related to confidential business documents play an important role in any medical device products liability case, including this MDL. They facilitate efficient document production and reduce the number of collateral discovery disputes, while also limiting dissemination of confidential information to those who are direct stakeholders in the litigation. Accordingly, Defendants C.R. Bard, Inc. and Davol Inc. (collectively “Bard”) move the Court to adopt the attached Protective Order (attached as Exhibit 1), which the parties are in near agreement on. One dispute remains, on which the Court heard initial argument at the October 10, 2018, Case Management Conference. The Court requested the parties file contemporaneous briefs. *See* ECF No. 24.

The parties agree that Bard’s confidential documents relating to, among other things, manufacturing and design processes for its products and other confidential and trade secrets, should be protected by a formal Protective Order. The only remaining issue is one sentence related to whether a third-party witness—most likely, but not only, treating physicians—may be shown Bard’s confidential documents at deposition without first signing the Protective Order. Bard’s position is that third-party witnesses, including experts and treating physicians, must sign

the Protective Order and agree to its terms before being shown Bard's confidential documents by Plaintiffs. Only by protecting the integrity of the *process* can there be a justification for wide scale production of documents without numerous disputes over the relevance of many documents which otherwise will be produced under an appropriate protective order. Plaintiffs contend that it is sufficient if such a witness generally affirms in a deposition at some point after being shown Bard's confidential documents that the witness "will keep the information confidential."

There is no inherent right of a third-party witness to see confidential plaintiff or defendant information, whether at a deposition or elsewhere. Davol anticipates that Plaintiffs may seek *ex parte* meetings with treating physicians in advance of a deposition as is their right under many state laws. But the permissible scope of *ex parte* meetings have been, and will be, an area of dispute among plaintiffs and defendants. Indeed, numerous courts have weighed in when pre-deposition meetings with treating physicians go beyond discussions of the witnesses' care and treatment of the plaintiff and venture into plaintiff's theories of liability.<sup>1</sup>

Clearly there is no obligation for a treating physician to meet with the lawyer for either party under these circumstances. Similarly, a physician may be willing to discuss a plaintiff's medical facts with his or her counsel, but not be willing to view internal company documents and engage in speculation about documents they have never seen before in an *ex parte* meeting, especially without first conferring with his or her own counsel. A third-party can be compelled to appear for deposition under subpoena, but cannot be compelled to participate in an *ex parte* meeting or take any particular position on being bound by a Protective Order in connection with

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<sup>1</sup> The potential for abuse and unfairness in *ex parte* meetings with physicians have been highlighted in other MDL court opinions. *See, e.g., In re Ortho Evra Prod. Liab. Litig.*, No. 1:06-40000, 2010 WL 320064, at \*2 (N.D. Ohio Jan. 20, 2010) ("Plaintiffs' counsel may meet *ex parte* to discuss the physicians' records, course of treatment and related matters, but not as to liability issues or theories, product warnings, Defendant research documents or related materials.").

such a meeting or a deposition. And surely third-party witness certainly cannot be compelled to forego seeking the advice of counsel in connection with being a witness.

To be clear, Bard is not arguing that Plaintiffs cannot show third-party witnesses any of Bard's confidential documents—even though they do not have anything to do with the care and treatment of any given plaintiff. Rather, Bard offered a compromise which allows Plaintiffs the ability to show witnesses confidential documents but only *after* the witness has signed off on the Protective Order and all of the responsibilities and obligations that go along with *any* protective order. Requiring that the witness make a decision on whether to sign the Protective Order *before* being shown Bard's confidential documents is necessary for several reasons.

***First***, if the third-party witness elects to sign the Protective Order and acknowledge that he or she will strictly adhere to the contents of the Order, keep the documents confidential, and not copy, disclose or otherwise use such material and be subject to the jurisdiction of this Court, then a legal agreement is established and Bard has a clear path for recourse if the witness violates the Court Order. By showing the witness the Protective Order and asking the witness to sign it, he or she has the opportunity to read the entire Protective Order, seek advice of counsel if the witness so chooses, and understands that this is a formal Court document. If the witness decides not to sign, then that decision must be respected.<sup>2</sup>

***Second***, by signing the Protective Order, the third-party witness acknowledges being subject to this Court's jurisdiction if the Protective Order is violated. Third-party witnesses will be located in jurisdictions all across the United States and signing the Protective Order establishes for the witness that this is a formal Court order and if violated the witness is subject

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<sup>2</sup> See, e.g., Ohio Rule Of Professional Conduct 4.4(a) ("In representing a client, a lawyer shall not use means that have no *substantial* purpose other than to embarrass, harass, delay, or burden a third person, or use methods of obtaining evidence that violate the legal rights of such a person.").

to this jurisdiction of this Court, which will have the greatest interest in enforcing its own Protective Order. Leaving this determination to various federal and state courts across the nation, without any knowledge of this litigation, much less context of the issues at hand is a recipe for chaos and an abundance of collateral litigation.

An after-the-fact verbal acknowledgment that the witness “will keep the information confidential” does none of these things. Bard’s proposed Protective Order allows for a witness to sign an agreement acknowledging they are bound by the Protective Order and that the Court keeps jurisdiction. This formal process provides certainty to Bard, the witness, and the Court, which Plaintiffs’ proposed protective order does not do.

## **II. ARGUMENT**

### **A. Executing The Agreement To Maintain Confidentiality Is Necessary To Protect Bard’s Proprietary Business Information**

Federal Rule of Civil Procedure 26(c) allows a party to move for a protective order to facilitate the production of documents and other discovery in this matter and to protect, among other things, “trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a specified way” or other proprietary business information. Fed. R. Civ. P. 26(c). *See also Wedgewood Ltd. P’ship I v. Twp. of Liberty*, No. 2:04-CV-1069, 2007 WL 1796089, at \*3 (S.D. Ohio June 21, 2007) (citing *Seattle Times Co. v. Rhinehart*, 467 U.S. 20, 34–35 (1984)). This would include protecting business information on the ground that it is commercially sensitive and would cause harm if known by a competitor.

The parties agree that Bard’s documents should be kept confidential.<sup>3</sup> Likewise, the parties agree that third-party witnesses, like treating physicians, should not be shown Bard’s

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<sup>3</sup> Under the terms of the Protective Order, any party disclosing information may make a designation that information merits protection under the terms of the Protective Order, and any other party may challenge that designation. If the parties are unable to resolve the dispute, then the matter may be submitted to the Court for resolution.

confidential documents without memorializing the agreement to keep them confidential. Plaintiffs, however, propose a special rule for such witnesses to aid in the ex parte meetings they would like to have in advance of any depositions. By contrast, Bard's proposed language would ensure fairness to third-party witnesses and the parties.

The Protective Order proposed by Bard provides that confidential information may be disclosed to witnesses, as long as prior to the disclosure "the disclosing party will provide each potential recipient of Confidential Information with a copy of this Protective Order, which said recipient shall read. Upon reading this Protective Order, such person shall sign an Acknowledgment, annexed to this Protective Order as **Exhibit A**, acknowledging that he or she has read this Protective Order and shall abide by its terms." Exhibit 1, Protective Order at ¶ 14. The Protective Order carves out witnesses represented by counsel for Bard. *Id.* Plaintiffs would like a similar carve out for any other witnesses that "verbally agrees on the record that he/she will keep the information confidential" and not need to sign off on the protective order before seeing/receiving confidential documents. Plaintiffs' position has several problems, practical and otherwise.

**First**, if the witness is merely asked during a deposition—and possibly, if not likely, after already seeing documents in an ex parte meeting—to "keep the information confidential" going forward, the witness may not understand that the Protective Order is an official Order of the Court or even understand what the Protective Order says or its terms. It would be no different than asking someone to verbally agree to a contract retroactively without reviewing the contract or giving time to confer with counsel. This would not be fair to third-parties.

**Second**, while a witness may state on the record that they intend to keep Bard's documents confidential, Bard has no recourse if the witness does not (or has not, in the case

where documents were shown/provided in advance of any deposition). Indeed, if the witness is never deposed after being shown documents in an ex parte fashion, then no intent to be bound will be recorded at all. Even if there is ultimately a deposition of a third-party physician after an ex parte meeting with Plaintiffs during which Bard's confidential documents are shown, the timing allows improper dissemination of the documents or their content. For instance, some physicians may consult with Bard's competitors on surgical mesh products or have contact with the competitors' sales representatives. Such a physician could disclose to Bard's competitors documents or information related to Bard's manufacturing practices, new technologies, or issues with Bard's products, all that could cause severe financial harm to Bard. Witnesses could also share Bard's confidential information with the press. The possibility of a forward-looking verbal agreement to keep documents confidential—assuming there is a deposition and the witness assents—is insufficient to protect Bard.

Witnesses may not even know they are violating the Protective Order because they may either not realize the formality or requirements of the Protective Order, including that it precludes verbally sharing the contents of confidential documents with others. The wiser course is to only permit documents to be shown if a formal acknowledgement of the Protective Order has already occurred. Once a confidential document is shown there is no going back. Having a formal written agreement in place provides more structure. It also allows witnesses to seek the advice of counsel in advance of a deposition on whether they should sign the document. This protects the witness from being asked on the record whether they agree to something that they may not fully understand and does not give them an opportunity to seek legal advice.

Without a written agreement in place, Bard has little recourse. A verbal agreement on the record at a deposition, if one ever occurs, that the witness “will keep the information

confidential,” without more, is simply not enough to enforce the provisions of the Protective Order.

**B. By Signing The Agreement to Maintain Confidentiality This Court Has Jurisdiction To Enforce The Protective Order**

The Protective Order provides that “All persons receiving or given access to Confidential Information in accordance with the terms of this Order consent to the continuing jurisdiction of this Court for the purposes of enforcing this Order and remedying any violations thereof.” Exhibit 1, Protective Order at ¶ 15. *See also id.* at ¶ 23 (providing that “The Court shall have continuing jurisdiction over the terms and provisions of this Protective Order.”). The Agreement to Maintain Confidentiality—which in Bard’s view should to be signed by all witnesses or individuals before receiving/viewing confidential documents—extends the Court’s jurisdiction to all individuals who sign the agreement, no matter where they reside:

I understand that my unauthorized disclosure of any “Confidential Information” may constitute contempt of court and I agree to be personally subject to the jurisdiction of this Court for the purpose of enforcing my obligations under this Agreement, the Order, and any contempt proceeding that may be instituted for my violation of the terms of this Acknowledgment and the Protective Order.

*Id.*, Agreement to Maintain Confidentiality

This is also consistent with the case law. A “contempt proceeding must occur in the issuing jurisdiction because contempt is an affront to the court issuing the order.” *Waffenschmidt v. MacKay*, 763 F.2d 711, 716-17 (5th Cir. 1985); *Wilson v. United States*, 26 F.2d 215, 218 (8th Cir. 1928). *See also Bedgood v. Cleland*, 554 F.Supp. 513, 517 (D. Minn. 1982) (“[T]he power of a court to make an order carries with it the equal power to punish for a disobedience of that order, and the inquiry as to the question of disobedience has been, from time immemorial, the special function of the [ordering] court. . . . To submit the question of disobedience to another tribunal, be it a jury or another court, would operate to deprive the proceeding of half its

efficiency . . . . [T]he sole adjudication of contempts, and the punishments thereof [belong] exclusively . . . to each respective court”) (citation omitted, alterations in original). A court may therefore hold a party who violates a court order in contempt, regardless of the state in which the person violates the court’s orders. *Leman v. Krentler-Arnold Hinge Last Co.*, 284 U.S. 448, 454 (1932) (“This is one of the decencies of civilization that no one would dispute.”).

Plaintiffs proposed verbal agreement does not discuss with the witness which court would enforce a breach of the agreement nor does it bestow jurisdiction to any court. This is particularly true where a witness may not even fully contemplate that a violation of the Protective Order may subject the witness to a contempt proceeding. Under Plaintiffs’ proposal, Bard might have to attempt to enforce the Protective Order in various jurisdictions—to the extent it can without a formal agreement in place—undercutting this Court’s authority to enforce its orders and do so consistently. Bard should not be saddled with this burden or risk. Requiring a formal signed agreement avoids these jurisdictional issues, as well as any issue that the witness does not understand that the Protective Order is an official Court document or what its terms state.

### **C. Plaintiffs’ Anticipated Arguments Against Formality Lack Merit**

*First*, Plaintiffs may claim, as they did at the Case Management Conference, that the learned intermediary doctrine is an affirmative defense, which Bard has the burden to establish. This is not true. The learned intermediary doctrine is a substantive rule that outlines the legal duty to warn for a prescription product runs to the doctor, not the patient or public. *Vaccariello v. Smith & Nephew Richards, Inc.*, 763 N.E.2d 160, 164 (Ohio 2002) (“The learned intermediary doctrine does not relieve the manufacturer of liability to the ultimate user for an inadequate or misleading warning; it only provides that the warning reaches the ultimate user through the



learned intermediary.”). *See also* Ohio Rev. Code §2307.76(c) (codifying the learned intermediary doctrine).<sup>4</sup> The fact that Plaintiffs will have the burden of establishing proximate cause for failure to warn does not allow them to trample on the rights of the third-party prescribing physicians whose testimony they need. Although Plaintiffs may prefer to show confidential documents to these physicians in ex parte meetings or in deposition in an attempt to elicit deposition testimony that the doctor would not have prescribed the product had he or she been provided additional information, the physicians can refuse a meeting, refuse to review documents off the record, or refuse to be bound by a Protective Order, all based on the advice of counsel if desired. Plaintiffs will have to live with any such decisions. Nothing about their desire to prove proximate cause for an alleged failure to warn should allow Plaintiffs to essentially put third-party physicians in the position of not understanding or being allowed to exercise their rights. Bard’s proposal ensures fairness to third-parties whereas Plaintiffs’ proposal subjugates it to expediency.

***Second,*** Plaintiffs may also argue that Bard may show its confidential documents to witnesses like former sales representatives it represents in connection with depositions. This is a red-herring, because Bard can choose to show its own documents to anyone. Moreover, sales representatives are past or current employees and have other agreements in place to retain confidentially. Showing a Bard employee, current or former, confidential documents is far different from showing a third-party physician confidential documents. Although it has no obligation to have its former employees sign a protective order, as a compromise, Bard will agree to use its best efforts to request that all former employees its counsel represents sign the Protective Order before being shown confidential documents at deposition or otherwise.

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<sup>4</sup> The state substantive law that would apply to any given plaintiff would depend on the state that the product was prescribed, however, for the purposes of this motion, Bard cites Ohio state law—although the definition of the learned intermediary doctrine is similar in virtually all jurisdictions.

### III. CONCLUSION

Defendants C. R. Bard, Inc. and Davol Inc. respectfully request that the attached Protective Order (Exhibit 1) be entered.

Dated: October 17, 2018

Respectfully submitted,

/s/ William D. Kloss, Jr.

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**CERTIFICATE OF SERVICE**

I hereby certify that on October 17, 2018, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice to all counsel of record.

/s/ William D. Kloss, Jr. \_\_\_\_\_

William D. Kloss, Jr.